

IRB: _____
Protocol #: _____
Date: _____
Reviewer: _____

Informed Consent/Assent Checklist

MAINE CDC holds a FederalWide Assurance with the Office for Human Research Protections (formerly OPRR), DHHS, whereby MAINE CDC agrees to abide by the requirements of Title 45 Code of Federal Regulations for the Protection of Human Subjects (45 CFR 46).

Section 116 (§46.116) of the federal regulations gives the general requirements for informed consent. The section reads, in part, "...no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject..."

The purpose of this checklist is to aid you in your evaluation of the informed consent documents accompanying each protocol to assure that those required elements are included. Please use the blocks to make notes or simply check that the basic requirement has been satisfactorily addressed.

All consent documents must address the following three principles:

Requirement	45 CFR 46.116	Consent/ Permission/ Adolescent form	Child Assent Form
<i>Voluntariness</i>	A. "An investigator shall seek...consent only under circumstances that provide the prospective subject...sufficient opportunity to consider whether or not to participate..."		
	B. "...and minimize the possibility of coercion or undue influence."		
<i>Comprehension</i>	"The information...given to the subject...shall be in language understandable to the subject..." The reading grade level and method (SMOG, Fry, Flesch-Kincaid) used to determine the reading grade level must be specified.	Grade level: ____ SMOG: ____ Fry: ____ F-K: ____	Grade level: ____ SMOG: ____ Fry: ____ F-K: ____
<i>Coercion</i>	No informed consent... may include any exculpatory language through which the subject...is made to waive...any of the subject's legal rights, or releases the investigator, the sponsor or the institution ...from liability for negligence.		

Required Elements of Informed Consent

The Federal Regulations at §46.116 describes eight elements required in each consent document. Element number six is only required if the research is determined to be greater than minimal risk. This section also lists an additional six elements that "When appropriate...shall also be provided to each subject."

Please use the following determination key when evaluating each element:

- Y** = appropriately included in the consent form
N/A = element not required for this study (IRB must waive and document)
M = element missing (the consent form must be revised to include this element or the requirement must be waived by the IRB)
I = incomplete or problematic

Element	45 CFR 46.116(a)	Consent/ Permission/ Adolesent Form	Child Assent Form
1	A. a statement that the study involves research		basic*
	B. an explanation of the purposes of the research		basic*
	C. the expected duration of the subject's participation		basic*
	D. a description of the procedures to be followed		basic*
	E. identification of any procedures which are experimental		generally not needed
2	a description of any reasonably foreseeable risks or discomforts to the subject		stress immediate risks/benefits rather than future or theoretical risks/benefits
3	a description of any benefits to the subject or to others which may reasonably be expected from the research		
4	a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject		generally not needed
5	a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained		generally not needed
6	A. an explanation as to whether any compensation is available if injury occurs		generally not needed
	B. an explanation as to whether any medical treatments are available if injury occurs, and, if so		
	C. what they consist of or where further information may be obtained		

Element	45 CFR 46.116(a)	Consent/ Permission/ Adolescent Form	Child Assent Form
7	A. an explanation of whom to contact for answers to pertinent questions about the research		suggest talking to parents/doctor/researcher
	B. an explanation of whom to contact for answers to pertinent questions about the research subjects' rights		generally not needed
	C. whom to contact in the event of a research-related injury to the subject		
8	A. a statement that participation is voluntary		basic*
	B. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled		generally not needed
	C. the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled		stress option to discontinue at any time

Additional elements (45 CFR 46.116(b) of informed consent (when appropriate, one or more of the following elements of information shall also be provided to each subject):			
1	a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable		generally not needed
2	anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent		
3	any additional costs to the subject that may result from participation in the research		
4	A. the consequences of a subject's decision to withdraw from the research		
	B. procedures for orderly termination of participation by the subject		
5	a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject		
6	the approximated number of subjects involved in the study		

*basic: brief and simple explanation

General Guidelines for Developing Assent Forms for Participation in MAINE CDC Research Activities

The federal regulations that govern the protection of human subjects involved in research state that adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians (45 CFR 46.407 and .408). Generally, MAINE CDC IRBs require that the assent of a minor child be sought when the child is seven years of age or older, unless the child's decision-making capacity is impaired.

For children 7 to 11 years of age, the assent form should be simple enough for the child to understand what he/she is agreeing to do. In general, it should briefly explain in basic terms:

- that they are being asked to participate in a research study;
- the purpose of the study;
- an estimate of how much time is involved in participating;
- what will happen to them if they agree to participate (e.g., "draw some blood");
- the foreseeable risks and/or discomfort and any benefits they may experience (should stress the immediate risks and/or discomfort and benefits, rather than future or theoretical possibilities);
- that they should ask their parents or the doctor or researcher any questions they have about participating;
- that their participation is voluntary, and that they may discontinue participation at any time;
- that their father/mother/guardian has said that it's all right for them to participate.

For adolescents between the ages of 15 and 17, the assent form should closely follow the consent form used for consenting adult participants. Please see 45 CFR 46.116(a) for the basic required elements of informed consent that should be included in adult and adolescent (ages 15 to 17) consent forms.

For children between the ages of 12 and 14, investigators should use their judgment in deciding which of the required elements of informed consent (outlined in 45 CFR 46.116(a)) would be most appropriate for their study population.